REMARKS

1. Claims 49-69 are pending in the application. Independent Claims 49 and 60 are currently amended. Claims 50-59 and 61-64 are unchanged. Claims 67-69 are new.

Pending Claims 49-69 Are Entitled to Priority of Parent Application

2. The subject matter of the claims prior to this amendment in the instant application was a subset of the scope of the subject matter disclosed in the parent application. For example, originally-filed Claim 1 of the parent application did not require a step of determining the initial status of the cell cycle, whereas originally-filed Claim 2, which was dependent on Claim 1, added that limitation.

3. Nevertheless, to address any question and in an effort to complete the prosecution of this application, Applicant is amending the claims in this application to resolve this new ground of rejection.

4. In particular, pending independent Claims 49 and 60 are amended to clarify that they are directed to: "A method for treating a chemically sensitive individual having an irregular cell cycle for T lymphocytes, the method comprising the steps of: …." This language of the amendment is fully supported throughout the parent application, including, for example, at page 4, lines 6-7; at page 6, lines 1-23; and at page 10, lines 6-14. Claims 49 and 60 are further amended to include the step of: "determining an initial status of the cell cycle for T lymphocytes." This language for the amendment is fully supported throughout the parent application, including, for example, at page 1, line 8 – page 2, line 12; at page 4, line 11 – page 6, line 23; and at originally-filed Claims 1-2, 5-7, 22, and 24-26; and the Abstract.

5. New Claims 67-69 in the present application are dependent on independent Claim 49. New Claims 67-69 are supported by the parent application, including, for example, at originally-filed Claims 5-7 thereof, and are also supported by the disclosure of the present application. New Claims 67-69 are directed to more particular embodiments of the invention directly supported by the parent application and believed to be independently patentable.

6. In the parent application, at page 1, lines 1-12, it states: "… the starting point information relating to an individual's cell cycle can be used to scientifically and objectively monitor the effects on the individual's cell cycle of clinical treatment." At page 2, lines 25-28, it states: "The regulatory effect of the treatment on the cell cycle is preferably objectively measured by subsequently determining the comparative changes in the patient's cell cycle

and hematological and immunological profiles." At page 9, lines 5, it states: "Initial clinical testing indicates that a first treatment of four properly diluted doses of ALF (4 X 0.1 ml) injected subcutaneously can have a significant regulatory effect on the individual's cell cycle. The regulatory effect can be objectively measured by determining the individual's cell cycle after the initial therapeutic treatment. This later cell cycle determination provides further indication of whether further treatment with ALF would be beneficial and the dosage that should be used." At page 9, lines 19-20, it states: "The initial test group included 250 individuals. Twenty-five of these individuals were normal controls." At page 10, lines 8-22, it describes the results of the clinical testing:

> The 250 individuals that were investigated in this study were affected principally by environmental incitants found in categories such as food, inhalants, and chemicals. They presented histories of varied backgrounds, but common among them was that all showed irregular cell cycles. The DNA histogram cycles showed over or under accumulation of lymphocytes in one or more phases of the cell cycle of each individual. The T lymphocytes of the affected individual are "stuck" in a particular phase, resting, synthesizing, or multiplying too much in the G0-G1, S, G2M phase respectively, the individual thereby manifesting symptoms peculiar to the phase(s) affected.
>
> Significant changes were observed within three weeks in patients treated with ALF. Changes were observed in overall clinical manifestations and immune regulations. With regard to clinical manifestations, minimal symptoms continued after approximately three weeks of continued therapy with ALF. Immunologically, there were significant regulations of cell cycles, especially from one phase of the cycle to another. Patients became less sensitive and more tolerant to specific incitants. *As treatment continued, in general, in about six weeks a more drastic shift toward that of a normal profile was observed.* (*Emphasis added.*)

7. The parent application discloses in Figure 1 a diagrammatic representation of normal DNA distribution for a cell cycle; in Figures 2a and 2b examples of normal and control histograms representing cell cycles; and Figures 3a, 3b, and 3c are examples of three different abnormal histograms representing cell cycles. It is true that the sample "case history" of Figures 4a, 4b, and 4c in the parent application has the cell cycles shown out of the actual order. That was the result of a mistake where Figures 4b and 4c in the parent application had been inadvertently reversed, which error was corrected in the present application. Nevertheless, the text of the written description in the disclosure of the parent application cannot fairly be ignored. In the disclosed clinical study involving 250 people, as treatment continued, it was reported that, in general, in about six weeks a more drastic shift toward that of a normal profile was observed, and that other clinical manifestations improved.

Further, the diagrammatic representation of a normal DNT histogram (which is well known), examples of normal histograms, and examples of abnormal histograms were provided. See Paragraph 6, above. Despite the error in Figures 4a, 4b, and 4c in the parent application, the specification made it clear that the method achieved the desired results, and it reasonably showed one skilled in the art how to do so. See *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996).

9. The subject matter of the pending Claims 49-69 is supported by the parent application and should be entitled to the priority of the parent application.

10. Regarding any public use or on-sale bar, Applicants report that they did not begin working on the invention as disclosed in the parent application until about November or December of 1993, and no publication or on-sale activity of the invention occurred prior to January 30, 1994, the applicable bar date based on the priority of the filing date of January 30, 1995 of the parent application. No further investigation or report beyond the applicable bar date should be necessary and has not been undertaken.

11. As this amendment moots the availability of Griffiths cited in the Office Action, which was dated prior to the applicable bar date based on the priority of the filing date of the parent application, a detailed analysis of the rejections based on Griffiths should not be necessary and has not been undertaken.

Conclusion

12. The pending Claims 49-69 are believed to be patentable and in condition for allowance, and such action is respectfully requested. Applicant requests that the Examiner help the undersigned bring the long prosecution of this application to a favorable conclusion. If a telephone interview would help conclude any matters of form or otherwise, the undersigned would sincerely appreciate a telephone conference and can normally be reached at the office telephone number below or can normally return a call within one business day.

DATED: February 26, 2007

CERTIFICATE OF MAILING

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